

assumptions are explored. Further assurances of internal validity include the replication of the model in another software. **CONCLUSION:** Approaches to model validation should be included as part of any publication. Budgetary and time allocation should take model validation into account given the increased importance placed on the outcomes of health economic models.

**PMC34****BIBLIOGRAPHIC REVIEW OF DISCRETE EVENTS SIMULATION STUDIES IN HEALTH TECHNOLOGY EVALUATION**

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**OBJECTIVES:** The use of computational models to assess therapeutic alternatives has been growing in importance in the economic evaluation of health technologies and services during the last years, becoming a more relevant and helpful tool for decision making in health care. Until now, two types of models have been used: decision trees and Markov chains, nevertheless, they both show important limitations when addressing complex processes or pathologies, and that's why interest in, and use of discrete event simulation (DES) is growing, specially in economic evaluation and medical decision making related journals. The objective of this study was to perform a bibliographic review of DES studies, and to evaluate their advantages and limitations where compared with other broadly used decision analytic model techniques. **METHODS:** A structured bibliographic search using Medline, principally, was performed to search in the scientific literature the keywords: Health technology, computer simulation, economic evaluation models and discrete event simulation. A system of selection of the search based on authors peer reviews and expert criteria was established. **RESULTS:** Forty-two papers were selected using DES alone or combined with Markov chains and decision trees. The result reflects the increasing number of the DES in after 1998, specially in the last 5 years. A classification of the selected articles was performed. These classification revealed the use of secondary data in these model development. Studies come in a highest percentage from UK, USA, and Holland, the temporal perspective was from less than 1 up to 50 years; sensitivity analysis was performed in the mentioned studies and Simul8, Arena, MS Excel were the most frequent used softwares. **CONCLUSION:** The results reflect that the use and acceptance of DES is growing internationally in health technology and health care analysis, so it would be an useful tool to simulate some complicated system and processes.

**MUSCULAR-SKELETAL DISORDERS—Cost Studies****PMS1****DIRECT HEALTH COSTS OF TREATING PATIENTS WITH FIBROMYALGIA IN PRIMARY CARE SETTINGS (PCS) UNDER ROUTINE MEDICAL PRACTICE: A COST OF ILLNESS STUDY USING A CLAIM DATABASE IN SPAIN**

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**OBJECTIVES:** To analyze a health resources utilization claim database in order to derive direct health costs of treating patients with Fibromyalgia under routine medical practice at PCS. **METHODS:** A 12-month retrospective study was performed using computerized medical records from a health provider database; BSA. Analysis was conducted from a 3r-payer perspective

during the year 2006. Health resources utilization included both those of the primary care (PC) level (drugs, complementary tests, medical visits, etc.) and those of the specialized care (SC) as well. SC included emergency visits, hospitalizations, and tests and drugs prescribed by specialist. Men and women above 18-years included in the data base (n = 63,526) were analyzed. Fibromyalgia was diagnosed according with CIE-10 criteria. Descriptive statistics and ANCOVA models were used. **RESULTS:** One-thousand-eighty-one subjects [96.7% women, 54.2 (10.1) years] fulfilled CIE-10 criteria for Fibromyalgia amongst the 63,526 database subjects: 1.7%. Charlson index was no different in Fibromyalgia patients vs controls (the rest of sample analyzed), p = 0.212. After adjusting by age and sex, yearly total health costs per patient were €614 higher (+66%) on average in Fibromyalgia than in controls; €1,550 (95% CI: 1,341–1,760) vs. €937 (927–945), p < 0.0001. Both PC and SC annual costs were significantly higher in Fibro patients; mean per patient adjusted difference of €395 (276–513, p < 0.0001) and €219 (74–364, p = 0.003), respectively. Total annual drug costs were considerably higher in patients with Fibromyalgia; €591 (485–696) vs. €361 (356–366), p < 0.0001. Age correlated moderate but significantly with yearly PC, drug and total per patient health costs; r = 0.324, 0.325, and 0.278, respectively, p < 0.001 in all cases. **CONCLUSION:** Compared with controls, subjects with Fibromyalgia were associated to higher annual total direct health costs in the primary care setting. Drugs represented a considerable portion of health resources costs devoted to these patients. Age, but not sex, was associated with higher costs.

**PMS2****PATIENT-REPORTED-OUTCOMES (PRO) AS A DRIVEN OF DIRECT HEALTH COSTS IN SUBJECTS WITH FIBROMYALGIA: A LONGITUDINAL RETROSPECTIVE PRIMARY CARE SETTINGS (PCS) CLAIM DATABASE ANALYSIS**

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**OBJECTIVES:** To analyze the impact of PRO measurements on longitudinal direct health costs when treating Fibromyalgia under routine medical practice at PCS. **METHODS:** Retrospective sub-analysis of subjects above 18-years, with Fibromyalgia according to CIE-10, included in a claim database (BSA), who received the point-administration of FIQ, EQ-5D and BPI questionnaires after 12-months of health resources utilization record and deriving total health direct costs. Resources included emergency visits, hospitalizations, complementary tests, drugs and medical visits occurred both at primary (PC) and specialized care (SC) level. **RESULTS:** One-thousand-eighty-one subjects [96.7% women, 54.2 (10.1) years] fulfilled CIE-10 criteria for Fibromyalgia amongst 63,526 subjects in the database. PRO questionnaires were administered to a random sample of 200 patients [97.5% women, 53.0 (8.5) years] showing no statistically differences in health resources utilization and costs vs. the other Fibromyalgia patients. Patient disease impact was severe [total FIQ; 71.7 (16.9)] showing weak but significant correlation with total annual health costs; r = 0.202 (p = 0.004). Work/domestic-interference BPI-item correlated significantly, but also weak, with PC, drugs and total health costs; r = 0.216, 0.218, 0.242, respectively (p < 0.01 in all cases). BPI sleep interference correlated slightly but significant with total costs; r = 0.203 (p = 0.004).

Severity of pain (BPI-item-3) was statistically associated with total annual health costs; €1255 (932), €1473 (1198) and €1950 (1391) for mild, moderate and severe pain respectively,  $p = 0.017$ . Walking (FIQ1g) and work/domestic (BPI5d) interference were positive predictors for per patient annual drug costs, while pain problems and 12-month health state change (EQ-5D items 4 and 6) were negative predictors ( $R^2 = 0.283$ ,  $p < 0.001$ ). **CONCLUSION:** In the primary care setting, annual per patient total direct health cost of Fibromyalgia showed weak but statistically significant association with patient disease interference and severity of pain. Less drug costs could be associated with poorer outcomes in term of health state change and level of pain.

## **OBESITY—Clinical Outcomes Studies**

POB1

### **IMPACT OF OBESITY UPON COSTS AND ANTIPSYCHOTIC DRUG USE IN THE ADULT POPULATION SEEN IN SPANISH PRIMARY CARE CENTERS**

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**OBJECTIVES:** To describe the association between obesity and costs and use of antipsychotic drugs (APDs) in patients seen by seven Spanish primary care teams (PCTs), under usual medical practice. **METHODS:** A retrospective, multicenter study was made with patients receiving APD treatment during year 2005. Obesity was considered according to W.H.O. as a body mass index (BMI)  $> 30 \text{ kg/m}^2$ . Main measurements included APD consumption, sociodemographics, comorbidity/episodes, Charlson index (severity), and costs (semi-fixed and variable, visits, diagnostic/therapeutic procedures, referrals and drugs). Descriptive statistics, logistic regression model and analysis of covariance (ANCOVA) with Bonferroni correction were applied. **RESULTS:** A total of 42,437 patients (age:  $50.9 \pm 17.8$  years, women: 59.9%) were included in the analysis. Obesity was present in 27.3% [CI: 26.9–27.7%], with a 1.3% receiving APDs (typical: 48.8%, atypical: 51.2%;  $p = \text{NS}$ ). Patients with obesity showed higher annual average of episodes ( $7.0 \pm 4.0$  vs.  $5.5 \pm 3.6$ ), visits ( $12.1 \pm 9.8$  vs.  $9.1 \pm 8.5$ ) and severity ( $0.5 \pm 0.7$  vs.  $0.3 \pm 0.6$ ),  $p < 0.001$ . In the logistic regression analysis, obesity was related to APD use (OR = 1.5; CI: 1.3–1.8), hypertension (OR = 2.4; CI: 2.2–2.5), diabetes (OR = 1.4; CI: 1.3–1.5) and dyslipidemia (OR = 1.3; CI: 1.2–1.4),  $p < 0.001$  in all cases. After adjusting, BMI was slightly higher in subjects on APD;  $27.8 \text{ kg/m}^2$  vs.  $27.4 \text{ kg/m}^2$ ,  $p = 0.002$ . Mean crude and adjusted (age, gender and comorbidities) annual costs were significantly higher in obese patients than in non obese; €980.89  $\pm$  1,467.49 vs. €637.64  $\pm$  1,244.49,  $p < 0.001$ , and €810.88 vs. €693.79,  $p < 0.001$  respectively. All components of per patient per year costs were higher in the group of obese patients,  $p < 0.0001$ . **CONCLUSION:** Obesity was associated with the use of APDs and the presence of hypertension, diabetes and dyslipidemia. No differences were found between using typical or atypical APDs. Obese patients presented more comorbidity, use of health resources and associated costs.

POB2

### **REDUCING GLOBAL CARDIOMETABOLIC RISK IN OVERWEIGHT OR OBESE INDIVIDUALS WITH DYSLIPIDEMIA: PROJECTED BENEFITS OF RIMONABANT IN A REAL WORLD POPULATION**

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**OBJECTIVES:** Clinical trials have demonstrated that rimonabant leads to significant improvements in cardiometabolic risk factors, including weight, waist circumference, lipids, and fasting glucose. This study translates these benefits into expected outcomes when rimonabant is administered to adults with dyslipidemia and a BMI  $> 27 \text{ kg/m}^2$  in addition to diet and exercise. **METHODS:** A discrete event simulation was developed to project outcomes in individuals at increased cardiometabolic risk. Data from the Health Survey of England are used to create simulated adults free of cardiovascular disease (CVD) and diabetes but who are overweight or obese and have either elevated triglycerides or low HDL. Equations derived from the RIO trials are used to calculate changes in individual cardiometabolic risk factors as a function of time, treatment and baseline risk factors. Treatments considered are diet and exercise alone or with the addition of rimonabant 20mg. The simulation determines when individuals develop CVD, diabetes, or microvascular disease (MVD) using published equations from Framingham, UKPDS and the San Antonio Heart Study. **RESULTS:** After one year, simulated patients on rimonabant lose an average of 4.4 kg compared to only 0.4 kg with diet and exercise alone. On average HDL levels increase by 0.07 mmol/L more with rimonabant; triglyceride levels fall by 0.27 mmol/L more. Over their lifetimes, 1000 rimonabant users experience 9 fewer CVD events, live 66 years longer, and avoid 334 years with diabetes. MVD events fall by 30. Extending treatment to 10 years results in 11% fewer CVD events and life expectancy gains of 234 years compared to one year of treatment. **CONCLUSION:** These results suggest that in overweight or obese patients with dyslipidemia, cardiometabolic risk factor improvements associated with rimonabant, which extend beyond those expected with diet and exercise alone, could translate to concrete health gains by preventing or delaying diabetes, MVD and acute CVD.

## **OBESITY—Methods and Concepts**

POB3

### **A PROBABILISTIC BAYESIAN MARKOV MODEL IN WINBUGS FOR THE ECONOMIC EVALUATION OF THE TREATMENT WITH ORLISTAT OF ITALIAN OBESE PATIENTS**

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**OBJECTIVES:** The WinBUGS software is a powerful tool to analyze data in the framework of the bayesian theory and has recently been shown useful in developing complex probabilistic Markov models. Despite some clear advantages, this technique has not been fully exploited in health economic evaluations. We developed a cost-utility and budget impact analysis of the use of orlistat in Italian obese patients through this innovative modeling approach. **METHODS:** A probabilistic Markov model has been developed to simulate outcomes of the obese Italian population after four years of orlistat treatment plus six years of follow-up. The efficacy of the treatment derives from the XENDOS study. The model integrates a Framingham Heart Study-based algorithm to estimate cardiovascular risk. The